

Remarks

In view of the above amendments and the following remarks, reconsideration and further examination are respectfully requested.

Claims 1-12, 18, 19, and 21 have been previously canceled. In this response, claims 13-17, 20, and 22-23 have been amended, and claims 24-33 have been added. Consequently, claims 13-17, 20, and 22-23 are currently pending and under consideration.

It is believed that new claims 24-33 are supported by the application as originally filed. For example, claims 23-27 and 33 are supported by FIGS. 1-5 and the accompanying description in the specification, such as starting at page 6, line 20; page 13; and elsewhere in the originally filed application. Claims 28, 29 and 30 are, for example, supported by FIGS. 3, 4, and 5, respectively. Claims 31 and 32 are for instance supported by the description on page 10 of the originally filed application.

In items 1-3 of the Office Action, claims 15, 16, and 20 were objected to due to a few minor informalities. Claims 15, 16 and 20 have been amended to correct the cited informalities.

In item 4 of the Office Action, claim 23 was “objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.” Initially, it should be noted that the Applicants’ representative is somewhat confused as to the basis for this objection. It appears that claim 24 is somehow mischaracterized as being a product-by-process in item 4 of the Office Action, and then for some reason, in item 4, a case was cited that concerns the obviousness standard for product-by-process claims (and not whether a dependent product-by-process claim further limits an independent claim). Moreover, no explanation was given as to why claim 24 does not further define the features in independent claim 13. In traversing this objection, it first should be noted that dependent claim 24 is clearly an apparatus claim, and not a product-by-process claim. Second, it is submitted that claim 24 further refines the features recited in independent claim 13. For instance, independent claim 13 does not specify the material composition of the holding area and the capillary structure; whereas, dependent claim 24 specifies that the holding area and the capillary structure are made of silicon. Therefore, it is clear that dependent claim 24 further defines the features of claim 13,

and the objection in item 4 is improper. For these and other reasons, it is requested that the objection to claim 24 in item 4 be withdrawn.

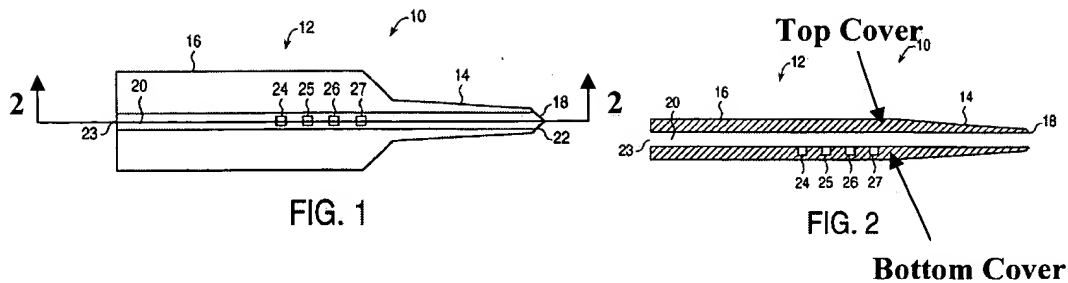
Claims 14-17, 20, and 22-23 have been amended to correct the informality cited in item 5 of the Office Action.

In item 7 of the Office Action, independent claim 13 was “rejected under 35 U.S.C. 103(a) as being unpatentable over Mauze et al. (6,375,627 B1) in view of Garcia et al. (US 4,637,403).” It is believed that independent claim 13, as amended, is allowable over the references of record. For example, both Garcia and Mauze fail to disclose all of the features recited in claim 13, and further, Mauze teaches away from such a combination of features recited in claim 13. For instance, both references fail to disclose “a distal end of the capillary structure defining a tip which is suitable for piercing skin” and “wherein the at least one capillary channel is open to the outside in an area which comprises at least a part of the longitudinal extension of the capillary structure extending beyond the distal end.” As recognized in previous Office Actions, Garcia fails to disclose such a feature.

It is submitted that Mauze likewise fails to disclose a capillary channel that is open to the outside. In item 8 of the Office Action, it was alleged:

Mauze et al disclose a sampling means with an open channel, as shown in Figure 1, where there are solid lines denoting the channel (20). If the channel were not open to the outside, the lines would be dashed lines and not solid.

However, it is submitted that the solid lines denoting the channel 20 in FIG. 1 of Mauze are simply a graphical error and do not show an open capillary channel of the type recited in claim 13. Moreover, after reading Mauze in its entirety, one of ordinary skill in the art would conclude that Mauze discloses only a closed capillary channel, especially since the rest of the drawings in Mauze show that channel 20 is in fact closed. To aid in the following discussion marked-up versions of FIGS. 1 and 2 from Mauze have been provided below.



Under the “Brief Description of the Drawings” section in Mauze, FIG. 2 was described as showing “a sectional view of the embodiment of a sampling needle of FIG. 1 according to the present invention.” Section line 2-2 has been added above to show the likely sectional view for FIG. 2. As can be seen in the marked-up version of FIG. 2, channel 20 is enclosed by top and bottom covers of the sampling needle, and thus, channel 20 is not open to the outside.

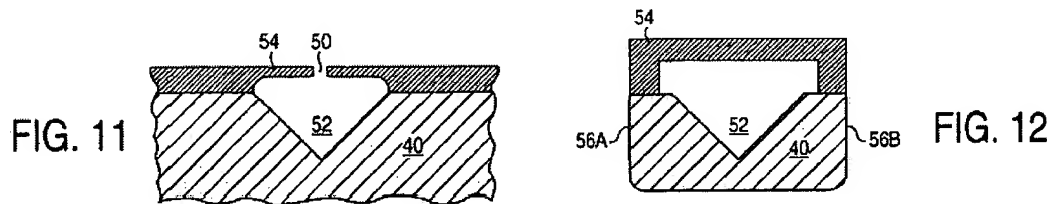
In addition, the specification of Mauze supports this view that the channel 20 is in fact closed or covered. Nowhere does the specification of Mauze expressly describe that channel 20 is open to the outside. Rather, the specification of Mauze expressly teaches that channel 20 is closed, and indeed, Mauze teaches away from utilizing an open capillary channel because such a feature would expose the fluid to air, which would change the properties of the fluid being analyzed. As stated in Mauze at column 4, line 56 to column 5, line 3:

Since the channel 20 is narrow and only a small volume of air (or gas if the channel has been purposely filled with a storage gas, such as nitrogen before sampling) is in contact with the proximal portion of the physiological fluid passing up the channel 20, the portion of the physiological fluid that eventually settles about the sensors 24-27 when the physiological fluid stops in the channel will not have exposure to air, and thus will have chemistry substantially similar to the physiological fluid in the physiological tissue. In this way, certain parameters of the physiological fluid which may be changed by exposure to air (e.g., gas content of blood) can be sampled and analyzed in vitro, without cumbersome and painful procedures such as inserting a catheter or needle into a vein of a patient.

If channel 20 was open in the manner as purported in the Office Action, fluid sample at the sensors 24-27 would be exposed to air, which is contrary to the teachings of Mauze.

As further evidence that channel 20 is covered, when illustrating and describing how to manufacture the sampling needle 10 using silicon integrated circuit (IC) techniques, Mauze goes on to explain in columns 6 and 7 that the sampling channel 52 (20) is covered by a Si_3N_4 layer

54. FIGS. 11 and 12 of Mauze, which have been provided below for the Examiner's convenience, clearly show that the channel is covered. FIG. 11 shows a sectional view of the plate portion 16 of the sampling needle 10, and FIG. 12 shows a sectional view of the shaft portion 14.



Looking at FIG. 11, channel 52 in the plate portion 16 of the sampling needle 10 is bounded by substrate 40 and Si_3N_4 layer 54. Openings 50 in the plate portion 16 permit etchants to gain access through the Si_3N_4 layer 54 and etch away a portion of the sampling chamber 52. As should be appreciated, if the channels were open channels as alleged in the Office Action, then the openings 50 for the etchants would not be necessary. It should be noted that the openings 50 are later apparently filled with sensing chemicals for analyzing the fluid sample, as is shown in FIG. 13 (see, column 7, lines 4-7 and column 11, line 60 to column 12, line 9). Regarding the shaft portion 14 of the sampling needle 10, which is shown in FIG. 12, Mauze at column 7, lines 11-12 specifically states “the sampling channel 52 is bounded by the substrate 40 and the Si_3N_4 layer 54.” More importantly, Mauze teaches away from having an open channel or any type of opening in the shaft portion 14 by stating that “[i]t is preferred that openings 50 be absent in the shaft portion to maintain the shaft stiffness to facilitate penetration into the physiological tissue of a patient.” Column 7, lines 14-17. For these as well as other reasons, Mauze fails to disclose an open capillary channel and further teaches away from such a feature.

In item 8 of the Office Action, it was commented that “[a]ssuming for arguments sake, that FIG. 1 does not disclose an open channel . . . Figure 1 still shows the distal end of the lancing device (18, 22) as a pointed end without anything covering the distal end [and therefore,] . . . the distal end would constitute an open channel, per the requirement of ‘at least one capillary channel is open to the outside in an area which comprises at least a part of the longitudinal extension of the capillary structure.’” In view of this comment, claim 13 has been amended to

further clarify that the area of the capillary channel that is opened to the outside extends beyond the distal end of the capillary structure. Therefore, it is believed that the comments in item 8 have been addressed.

Given that both Garcia and Mauze fail to disclose all of the features recited in claim 13 and Mauze teaches away from such features, independent claim 13 is not obvious in view of these references. For these and other reasons, it is submitted that independent claim 13 and its dependent claims are allowable over the references of record.

Independent claim 24 has been added in order to provide further protection. It is believed that claim 24 is allowable over the references of record. For example, both Garcia and Mauze fail to disclose “wherein the capillary groove opens longitudinally along the outside of the lancing tip to permit collection of the body fluid along the length of the lancing tip.” For this and other reasons, it is believed that independent claim 24 and its dependent claims are allowable over the references of record.

As a housekeeping matter, it should be noted that an Information Disclosure Statement (IDS) was submitted on February 11, 2005. A copy of the IDS has not been again supplied since it appears on public PAIR. It is respectfully requested that an initialed copy of this IDS be returned in the next communication from the Patent Office.

It also should be noted that an IDS has been submitted with this response. It is kindly requested that the Examiner return an initialed copy of the IDS form with the next communication from the Patent Office.

Regarding still yet another piece of housekeeping, it should be noted that a Power of Attorney to Prosecute Applications Before the USPTO for Roche Diagnostics Operations, Inc., a Statement Under 37 CFR 3.73(b) and a new Power of Attorney for this application have been enclosed with this response in order to update the Power of Attorney and correspondence address to the current customer number (41577). It is believed that the requirements to update the Power of Attorney for this application have been satisfied, but if additional documentation is required, the Examiner is invited to contact the undersigned by telephone to quickly resolve the issue.

A Supplemental Application Data Sheet (ADS) has been submitted with this response in order to update the spelling of an inventor's first name as well as to update the docket number,

power of attorney and correspondence address information. In particular, the first name for Mr. Koehler has been corrected to "Karl-Heinz." In accordance with MPEP 201.03 and 601.05, it is believed that the enclosed ADS satisfy the requirements to correct the spelling of an inventor's name, and therefore, a supplemental declaration is not required.

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action, but are simply provided to overcome the rejections made in the Office Action in the most expedient fashion.

In view of the above amendments and remarks, it is submitted that the present application is now in condition for allowance, and the Examiner is requested to pass the case to issue. If the Examiner should have any comments or suggestions to help speed the prosecution of this application, the Examiner is requested to contact the undersigned representative by telephone.

Respectfully submitted,

By 

Charles P. Schmal, Reg. No. 45,082
Woodard, Emhardt, Moriarty, McNett & Henry LLP
Bank One Center/Tower
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
(317) 634-3456